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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,558	10/03/2003	Thumplasseril V. John	IFF-63	2540
48080	7590	04/29/2010	EXAMINER	
INTERNATIONAL FLAVORS & FRAGRANCES INC. 521 WEST 57TH ST NEW YORK, NY 10019			CHEN, CATHERYNE	
ART UNIT	PAPER NUMBER			
	1655			
MAIL DATE	DELIVERY MODE			
04/29/2010	PAPER			

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/678,558	JOHN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 01 March 2010.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 3,4,40 and 41 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 3,4,40 and 41 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____. _____	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

Currently, Claims 3-4 and 40-41 are pending and examined on the merits.

Claims 1-2, 5-39, 42-50 are canceled.

### ***Election/Restrictions***

Applicant's election without traverse of the species tingling sensate, spilanthol, in the reply filed on Feb. 6, 2008 is acknowledged.

### ***Response to Arguments***

Applicant's arguments, filed March 1, 2010, with respect to Claims 3-4, 40-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Nakatsu et al. (US 6780443 B1) and Claims 3-4, 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakatsu et al. (US 6780443 B1) have been fully considered and are persuasive. The rejections of Claims 3-4, 40-41 have been withdrawn.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3-4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The mixture in Claim 3 is a product of nature because the chemicals are naturally mixed up together in *Piper longum* Linn. and the amount would be about 100% (see Applicant's Specification, page 2, last line).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Hebert et al. (US 6451354 B1).

Hebert et al. teaches 100 grams of dried berries of *Piper longum* Linn is pulverized and mixed to a homogenous mass (column 5, lines 7-11). The chemicals inherently occur because all the alkadienamides are present in *Piper longum* Linn extract (see Applicant's Specification, page 2, last line).

Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al. (J Agric Food Chem, 2002, 50: 3765-3767).

Yang et al. teaches dried fruit of *P. longum* were crushed and extracted twice with methanol and partitioned into hexane then organic solvents are dried (Materials and Methods, Extraction and Isolation). The claimed mixture would inherently be present because the Applicant's Specification uses extraction from crushed *Piper longum* as a source and uses the same solvent, hexane, to obtain the mixture (page 5, i; page 6, iv). The concentration of the mixtures would be about 100% because the extracts are dried.

Claims 3 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by JB Chem Pharm (RU 2157226 C2) with (<http://chemicalland21.com/lifescience/foco/dl-MENTHOL.htm>) teaching inherently features of JB Chem Pharm.

JB Chem Pharm teaches medicinal plants for preparation are *Piper longum* (Abstract, Novelty, page 1) and menthol are added for use in coughs (Abstract, Novelty, page 2). Menthol is a type of ingredient that imparts tingling sensation (General Descriptions & Applications, <http://chemicalland21.com/lifescience/foco/dl-MENTHOL.htm>). The chemicals inherently occur because all the alkadienamides are present in *Piper longum* Linn extract (see Applicant's Specification, page 2, last line).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-4 and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farooqi et al. (US 6264926 B1) and as evidenced by Rai (2004, *Mycoses*, 47: 479-481).

Farooqi et al. teaches formulation of herbal toothpowder or toothpaste (column 1, line 6) with *Piper longum*'s fruit in the form of powder is applied to dental caries (Table 1, no. 17) and *Spilanthes calva* plant is made into paste for toothache (column 3, Table 1, no. 23). These chemicals are plants that are employed for tooth care in India (Table 1, Title). *Spilanthes calva* intrinsically contain the chemical spilanthol (Rai, Introduction, right column, lines 5-7). The chemicals inherently occur because all the alkadienamides are present in *Piper longum* Linn extract (see Applicant's Specification, page 2, last line).

However, the references do not teach the components together and about 3-100% of the mixture.

Farooqi et al. does not teach all of the claimed ingredients in one composition. However, the reference does teach that each of the claimed ingredients is suitable for combination in a pharmaceutical composition. These chemicals are plants that are employed for tooth care in India (Table 1, Title). Thus, an artisan of ordinary skill would be reasonably expected that the claimed ingredient could be combined together to

produce a single pharmaceutical product. This reasonable expectation of success would motivate the artisan to combine the claimed ingredients together into a single composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising about 3-100% of the active agent combination for the following reasons. The references do teach the composition for oral use (see Applicant's Specification, paragraph 1). Farooqi et al. teaches formulation of herbal toothpowder or toothpaste (column 1, line 6) with *Piper longum*'s fruit in the form of powder is applied to dental caries (Table 1, no. 17). Thus, it would have been obvious to make a composition containing mixture of Claim 3 for use as a compound for oral use. Additionally, the amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient) is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, especially within the ranges taught by the reference. Thus, absent some demonstration of unexpected results from the claimed

parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

## **Conclusion**

No claim is allowed.

## **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner Art Unit 1655

/Michele Flood/

Primary Examiner, Art Unit 1655